

Rec'd PCT/PPR 20 JAN 2006 #5

892,280-499 (PC19461)

IN THE UNITED STATES PATENT & TRADEMARK OFFICE

APPLICANT: Ameriga Lazzarini et al EXAMINER: Unknown  
SERIAL NO.: 10/521,336 ART UNIT: Unknown  
FILED: July 12, 2004 CONFIRMATION NO. 9155.  
TITLE: ANTIBIOTIC 107891, ITS FACTORS A1 AND A2, PHARMACEUTICALLY  
ACCEPTABLE SALTS AND COMPOSITIONS, AND USE THEREOF

Response to Notification of Missing Requirements Under 35 U.S.C. 371 In the United States Designated/Elected Office (DO/EO/US)

Mail Stop: Missing Parts  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

This paper is in response to the Notification of Missing Requirements under 35 U.S.C. 371 in the United States Designated/Elected Office, dated November 29, 2005. In the Notification of Missing Requirements under 35 U.S.C. 371, the Office indicated that the Applicant must furnish within two (2) months from the date of this notice or by 32 months from the priority date for the application, whichever is later, the following:

- a) an Oath or declaration of the inventors, in compliance with 37 CFR 1.497 (a) and (b), identifying the application by the International application number and international filing date.

Adjustment date: 05/12/2006 SAHMED1 provide an initial computer readable form (CRF) copy of the "Sequence 01/26/2006 ATRAN1 00000084 230455 10521336  
01-FC:1617 130.00 CR  
Listing", an initial paper or compact disc copy of the "Sequence Listing", as  
01/26/2006 ATRAN1 00000084 10521336 well as an amendment specifically directing its entry into the application, as  
01-FC:1617 130.00 DA well as a statement that the content of the sequence listing information  
05/12/2006 SAHMED1 00000001 230455 10521336 recorded in computer readable form is identical to the written (on paper or  
01 FC:2617 65.00 DA compact disc) sequence listing and where applicable, includes no new matter,  
as required by 37 CFR 1.821-1.825.

Enclosed with this paper is an Oath and Declaration, which has been, executed in accordance with either 37 CFR 1.66 or 37 CFR 1.68 and a computer readable form (CRF) copy of the "Sequence Listing", an initial paper or compact disc copy of the "Sequence Listing", as well

as an amendment specifically directing its entry into the application, as well as a statement that the content of the sequence listing information recorded in computer readable form is identical to the written (on paper or compact disc) sequence listing and where applicable, includes no new matter, as required by 37 CFR 1.821-1.825.

Thus, all requirements for acceptance of the instant application under 35 U.S.C. 371 have been met.

Authorization hereby is given to charge any fee, which may be required, or credit any overpayment, to Deposit Account 23-0455.

Dated:

1/20/06

Respectfully submitted,

  
J. Michael Dixon  
Registration No. 32,410  
Warner-Lambert Company  
2800 Plymouth Road  
Ann Arbor, MI 48105  
Tel. (734) 622-1705  
Fax (734) 622-1553



## UNITED STATES PATENT AND TRADEMARK OFFICE

PC19461  
 UNITED STATES DEPARTMENT OF COMMERCE  
 United States Patent and Trademark Office  
 Address: COMMISSIONER FOR PATENTS  
 P.O. Box 1450  
 Alexandria, Virginia 22313-1450  
 www.uspto.gov

U.S. APPLICATION NUMBER NO.	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
10/521,336	Ameriga Lazzarini	892,280-499

34263  
 O'MELVENY & MYERS LLP  
 610 NEWPORT CENTER DRIVE  
 17TH FLOOR  
 NEWPORT BEACH, CA 92660

Date Mailed: 11/29/2005

RECEIVED

DEC 05 2005

O'Melveny & Myers LLP  
 Newport Beach, California

DUE DATE 11/29/2006

DOCKETED BY DLB

Respond to Office Action  
 Instruct Foreign Agent  
 Additional Comments Due

Note to Atty: Missing requirements due

INTERNATIONAL APPLICATION NO.

PCT/EP04/07658

I.A. FILING DATE	PRIORITY DATE
07/12/2004	07/18/2003

CONFIRMATION NO. 9155

371 FORMALITIES LETTER



\*OC000000017534421\*

## NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 U.S.C. 371 IN THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)

The following items have been submitted by the applicant or the IB to the United States Patent and Trademark Office as a Designated / Elected Office (37 CFR 1.495).

- Indication of Small Entity Status
- Copy of the International Application filed on 01/11/2005
- Copy of the International Search Report filed on 01/11/2005
- Preliminary Amendments filed on 01/11/2005
- Information Disclosure Statements filed on 01/11/2005
- U.S. Basic National Fees filed on 01/11/2005
- Priority Documents filed on 01/11/2005

O'Melveny &amp; Myers LLP

File: \_\_\_\_\_  
 Action Item: \_\_\_\_\_  
 Date Due: \_\_\_\_\_  
 Critical Date: \_\_\_\_\_  
 Attorney Path: \_\_\_\_\_  
 Docketed By: \_\_\_\_\_  
 Verified By: \_\_\_\_\_

The following items **MUST** be furnished within the period set forth below in order to complete the requirements for acceptance under 35 U.S.C. 371:

- Oath or declaration of the inventors, in compliance with 37 CFR 1.497(a) and (b), identifying the application by the International application number and international filing date.
- This application clearly fails to comply with the requirements of 37 CFR 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998). If the effective filing date is on or after September 8, 2000, see the final rulemaking notice published in the Federal Register at 65 FR 54604 (September 8, 2000) and 1238 OG 145 (September 19, 2000). Applicant must provide an initial computer readable form (CRF) copy of the "Sequence Listing", an initial paper or compact disc copy of the "Sequence Listing", as well as an amendment specifically directing its entry into the application. Applicant must also provide a statement that the content of the sequence listing information recorded in computer readable form is identical to the written (on paper or compact disc) sequence listing and, where applicable, includes no new matter, as required by 37 CFR 1.821(e), 1.821(f), 1.821(g), 1.825(b), or 1.825(d). If applicant desires the sequence listing in the instant application to be identical with that of another

DEC 13 2005

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U.S. PATENT AND TRADEMARK OFFICE

application on file in the U.S. Patent and Trademark Office, such request in accordance with 37 CFR 1.821(e) may be submitted in lieu of a new CRF.

- A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 CFR 1.821(e). If the effective filing date is on or after September 8, 2000, see the final rulemaking notice published in the Federal Register at 65 FR 54604 (September 8, 2000) and 1238 OG 145 (September 19, 2000). Applicant must provide an initial computer readable form (CRF) copy of the "Sequence Listing" and a statement that the content of the sequence listing information recorded in computer readable form is identical to the written (on paper or compact disc) sequence listing and, where applicable, includes no new matter, as required by 37 CFR 1.821(e), 1.821(f), 1.821(g), 1.825(b), or 1.825(d). If applicant desires the sequence listing in the instant application to be identical with that of another application on file in the U.S. Patent and Trademark Office, such request in accordance with 37 CFR 1.821(e) may be submitted in lieu of a new CRF.

**ALL OF THE ITEMS SET FORTH ABOVE MUST BE SUBMITTED WITHIN TWO (2) MONTHS FROM THE DATE OF THIS NOTICE OR BY 32 MONTHS FROM THE PRIORITY DATE FOR THE APPLICATION, WHICHEVER IS LATER. FAILURE TO PROPERLY RESPOND WILL RESULT IN ABANDONMENT.**

The time period set above may be extended by filing a petition and fee for extension of time under the provisions of 37 CFR 1.136(a).

Applicant is cautioned that correction of the above items may cause the specification and drawings page count to exceed 100 pages. If the specification and drawings exceed 100 pages, applicant will need to submit the required application size fee.

**For questions regarding compliance to 37 CFR 1.821-1.825 requirements, please contact:**

- For Rules Interpretation, call (571) 272-0951
- For Patentin Software Program Help, call Patent EBC at 1-866-217-9197 or directly at 703-305-3028 / 703-308-6845 between the hours of 6 a.m. and 12 midnight, Monday through Friday, EST.
- Send e-mail correspondence for Patentin Software Program Help @ [ebc@uspto.gov](mailto:ebc@uspto.gov)

Applicant is reminded that any communications to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above (37 CFR 1.5)

*A copy of this notice MUST be returned with the response.*

SHAKEEL AHMED

Telephone: (703) 308-9140 EXT 208

**PART 1 - ATTORNEY/APPLICANT COPY**

U.S. APPLICATION NUMBER NO.	INTERNATIONAL APPLICATION NO.	ATTY. DOCKET NO.
10/521,336	PCT/EP04/07658	892,280-499

FORM PCT/DO/EO/905 (371 Formalities Notice)

01-23-06 143 Rec'd PTO PTO 20 JAN 2006 CT/AB

#5

Customer No. 28880

Confirmation No. 9155

PTO/SB/21 (09-04)

Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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012006

17224

U.S. PTO

TRANSMITTAL  
FORM

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission

Application Number

10/521,336

Filing Date

JULY 12, 2004

First Named Inventor

Ameriga Lazzarini

Art Unit

Examiner Name

Attorney Docket Number

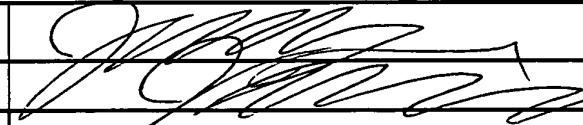
892,280-499 (PC19461)

## ENCLOSURES (Check all that apply)

<input checked="" type="checkbox"/> Fee Transmittal Form	<input type="checkbox"/> Drawing(s)	<input type="checkbox"/> After Allowance Communication to TC
<input type="checkbox"/> Fee Attached	<input type="checkbox"/> Licensing-related Papers	<input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences
<input checked="" type="checkbox"/> Amendment/Reply	<input type="checkbox"/> Petition	<input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief)
<input type="checkbox"/> After Final	<input type="checkbox"/> Petition to Convert to a Provisional Application	<input type="checkbox"/> Proprietary Information
<input type="checkbox"/> Affidavits/declaration(s)	<input type="checkbox"/> Power of Attorney, Revocation	<input type="checkbox"/> Status Letter
<input type="checkbox"/> Extension of Time Request	<input type="checkbox"/> Change of Correspondence Address	<input type="checkbox"/> Other Enclosure(s) (please Identify below):
<input type="checkbox"/> Express Abandonment Request	<input type="checkbox"/> Terminal Disclaimer	<input type="checkbox"/> Declaration and Power of Attorney
<input type="checkbox"/> Information Disclosure Statement	<input type="checkbox"/> Request for Refund	<input type="checkbox"/> Sequence Listing
<input type="checkbox"/> Certified Copy of Priority Document(s)	<input checked="" type="checkbox"/> CD, Number of CD(s) <u>1</u>	<input type="checkbox"/> Sequence Listing Certification
<input checked="" type="checkbox"/> Reply to Missing Parts/ Incomplete Application	<input type="checkbox"/> Landscape Table on CD	<input type="checkbox"/> Sequence Listing on CD
<input type="checkbox"/> Reply to Missing Parts under 37 CFR 1.52 or 1.53	Remarks	
Authorization to charge the fee and any additional fees as necessary or credit any overpayment to deposit account 23-0455 is hereby given.		

## SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name



Signature

Printed name

J. Micahel Dixon

Date

1/20/2006

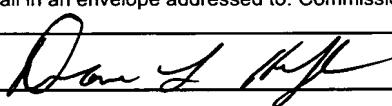
Reg. No.

32,410

## CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below:

Signature



Typed or printed name

Diane L. Hetzler

Date

1/20/2006

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

USPTO Fax No. 571-273-8300

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# FEE TRANSMITTAL for FY 2005

Effective 10/01/2004. Patent fees are subject to annual revision.

 Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT (\$130.00)

## Complete if Known

Application Number	10/521,336
Filing Date	July 12, 2004
First Named Inventor	Ameriga Lazzarini et al
Examiner Name	

Art Unit

Attorney Docket No. 892,280-499 (PC19461)

## METHOD OF PAYMENT (check all that apply)

 Check  Credit card  Money Order  Other  None
 Deposit Account:

Deposit Account Number 23-0455  
Deposit Account Name Warner-Lambert Company LLC

The Director is authorized to: (check all that apply)

Charge fee(s) indicated below  Credit any overpayments  
 Charge any additional fee(s) or any underpayment of fee(s)  
 Charge fee(s) indicated below, except for the filing fee to the above-identified deposit account.

## FEE CALCULATION

## 1. BASIC FILING FEE

Large Entity	Small Entity	Fee Code (\$)	Fee Code (\$)	Fee Description	Fee Paid
1001 790	2001 395			Utility filing fee	
1002 350	2002 175			Design filing fee	
1003 550	2003 275			Plant filing fee	
1004 790	2004 395			Reissue filing fee	
1005 160	2005 80			Provisional filing fee	
<b>SUBTOTAL (1)</b>		(\$0.00)			

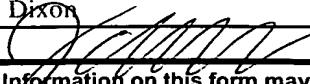
## 2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

Total Claims	Extra Claims	Fee from below	Fee Paid
	-20** =	x 18.00	=\$0.00
Independent Claims	- 3** =	x 88.00	=\$0.00
Multiple Dependent			

Large Entity	Small Entity	Fee Description
1202 18	2202 9	Claims in excess of 20
1201 88	2201 44	Independent claims in excess of 3
1203 300	2203 150	Multiple dependent claim, if not paid
1204 88	2204 44	** Reissue independent claims over original patent
1205 18	2205 9	** Reissue claims in excess of 20 and over original patent
<b>SUBTOTAL (2)</b>		(\$0.00)

\*\*or number previously paid, if greater; For Reissues, see above

3. ADDITIONAL FEES	Large Entity	Small Entity	Fee Description	Fee Paid
04/26/2006-ATRAN1	00000084-230455	10521336	01 FC-1617 130.00 DA	
Fee Code (\$)	Fee Code (\$)	Fee Code (\$)	Fee Description	Fee Paid
1051 130	2051 65	Surcharge - late filing fee or oath		130.00
1052 50	2052 25	Surcharge - late provisional filing fee or cover sheet		
1053 130	1053 130	Non-English specification		
1812 2,520	1812 2,520	For filing a request for ex parte reexamination		
1804 920*	1804 920*	Requesting publication of SIR prior to Examiner action		
1805 1,840*	1805 1,840*	Requesting publication of SIR after Examiner action		
1251 110	2251 55	Extension for reply within first month		
1252 430	2252 215	Extension for reply within second month		
1253 980	2253 490	Extension for reply within third month		
1254 1,530	2254 765	Extension for reply within fourth month		
1255 2,080	2255 1,040	Extension for reply within fifth month		
1401 340	2401 170	Notice of Appeal		
1402 340	2402 170	Filing a brief in support of an appeal		
1403 300	2403 150	Request for oral hearing		
1451 1,510	1451 1,510	Petition to institute a public use proceeding		
1452 110	2452 55	Petition to revive - unavoidable		
1453 1,330	2453 665	Petition to revive - unintentional		
1501 1,370	2501 685	Utility issue fee (or reissue)		
1502 490	2502 245	Design issue fee		
1503 660	2503 330	Plant issue fee		
1460 130	1460 130	Petitions to the Commissioner		
1807 50	1807 50	Processing fee under 37 CFR 1.17(q)		
1806 180	1806 180	Submission of Information Disclosure Stmt		
8021 40	8021 40	Recording each patent assignment per property (times number of properties)		
1809 790	2809 395	Filing a submission after final rejection (37 CFR 1.129(a))		
1810 790	2810 395	For each additional invention to be examined (37 CFR 1.129(b))		
1801 790	2801 395	Request for Continued Examination (RCE)		
1802 900	1802 900	Request for expedited examination of a design application		
Other fee (specify) _____				
*Reduced by Basic Filing Fee Paid				
<b>SUBTOTAL (3)</b>				(\$130.00)

(Complete if applicable)				
Name (Print/Type)	J. Michael Dixon	Registration No. (Attorney/Agent)	32,410	Telephone 734-672-1705
Signature			Date	1/20/06

**WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.**

This collection of information is required by 37 CFR 1.17 and 1.27. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Rec'd PCMA/ET 22 JAN 2006

Customer No. 28880

**CERTIFICATE OF MAILING BY "EXPRESS MAIL" (37 CFR 1.10)**

Applicant(s): Ameriga Lazzarini et al

Docket No.

892,280-499 (PC19461)

Serial No. 10/521,336	Filing Date 12-Jul-2004	Examiner	Group Art
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Invention:

ANTIBIOTIC 107891, ITS FACTORS A1 AND A2, PHARMACEUTICALLY ACCEPTABLE SALTS AND COMPOSITIONS, AND USE THEREOF

I hereby certify that this

**RESPONSE TO NOTICE TO FILE CORRECTED APPLICATION PAPERS**

*(Identify type of correspondence)*

Is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on January 20, 2006  
*(Date)*

Diane L. Hetzler

*(Typed or Printed Name of Person Mailing Correspondence)*



*(Signature of Person Mailing Correspondence)*

EV545394363US

*("Express Mail" Mailing Label Number)*

**Note: Each paper must have its own certificate of mailing**

1. TRANSMITTAL LETTER (1 PAGE)
2. FEE TRANSMITTAL (1 PAGE)
3. RESPONSE (2 PAGES)
4. PRELIMINARY AMENDMENT (3 PAGES)
5. PAPER COPY OF SEQUENCE LISTING (2 PAGES)
6. SEQUENCE LISTING CERTIFICATION (1 PAGE)
7. SEQUENCE LISTING ON COMPUTER READABLE CD
8. COPY OF THE NOTIFICATION OF MISSING REQUIREMENTS MAILED 11/29/2005 (2 PAGES)
9. DECLARATION AND POWER OF ATTORNEY (5 PAGES)
10. CERTIFICATE OF EXPRESS MAILING EXPRESS MAIL #EV545394363US (1 PAGE)
11. AUTH. TO DEBIT/CREDIT DEPOSIT ACCOUNT 23-0455
12. RETURN POSTCARD